REMARKS

Claims 1-5, 10-17, 23, 25, 26, 29-35, and 38-41 are pending in the present application. New claims 42-44 are presented. Claims 15 and 40 are amended to remove typographical errors. Support for the newly added claims is found throughout the specification, and in particular at page 17, paragraph [0051]. Therefore, these amendments do not add any new matter, raise any new issues, or require any further search. Their entry is respectfully requested.

Applicant files this response together with a Request for Continued Examination. The Advisory action dated November 19, 2007, indicated that applicant's previous amendment, dated August 29, 2007, had been entered; and withdrew the rejection of claims 1-5, 10-17, 23, and 29-37 under 35 U.S.C. § 112, first paragraph, written description.

Claims 1-5, 10-17, 23, 29-37, and 40-41 remain rejected under 35 U.S.C. § 112, first paragraph for lack of enablement.

The Examiner contends that administration of an ActRIIB-Fc fusion protein to an individual with a muscle or neuromuscular disease or disorder is not enabled by the specification, because applicants allegedly have not used the correct animal model for studying increasing muscle mass in Duchenne's muscular dystrophy (DMD). Advisory Action at 2. In particular, the Examiner states that the results presented in the first Yaworsky Declaration and in the Ohsawa reference, showing ActRIIB-Fc's in vivo efficacy in two different models of muscular disease or disorder, do not show enablement for increasing muscle mass in an individual with any muscular disorder, such as, for example, "complex genetic disorders like DMD," because the submitted "declaration is silent on the mdx model or on DMD." Advisory Action at 2.

Applicant emphasizes that the specification enables the claims for the reasons previously set forth in the August 29, 2007 reply. Moreover, the subsequently submitted evidence confirms this enablement. However, in order to expedite prosecution, Applicant attaches a second Declaration of Dr. Paul Yaworsky under 37 C.F.R. § 1.132 (Second Yaworsky Declaration). This declaration provides evidence that administration of an ActRIIB-Fc fusion protein that falls within the scope of the pending claims increases muscle mass in an *in vivo* animal model of muscular dystrophy, namely, the *mdx* mouse.

The experiments presented in the Second Yaworsky Declaration utilize *mdx* mice, which the Examiner has insisted is the only appropriate model for studying DMD (see, for example, Office Action mailed November 9, 2006, at page 8, ¶ 16, and Advisory Action at 2)*. Administration of the ActRIIB-Fc fusion protein increased both muscle strength and muscle mass in the *mdx* mice. Second Yaworsky Declaration at ¶¶ 5, 6. These studies clearly demonstrate that administration of an ActRIIB-Fc fusion protein increases muscle strength and mass in an *in vivo* animal model of muscular dystrophy. Second Yaworsky Declaration at ¶ 7.

Accordingly, these studies confirm the teaching of the specification, and the claimed invention, namely that administration of an ActRIIB-Fc fusion protein increases muscle mass in an individual with a disease or disorder in which an increase in muscle mass is desirable.

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* As noted in prior responses, Applicant disagrees for at least the reason that the claims encompass more than simply treatment of DMD.

For all of the reasons discussed above, and for the reasons discussed in Applicant's August 29, 2007, reply, the pending claims are enabled by the specification as filed. Therefore, the rejection of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement, should be reconsidered and withdrawn.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: March 5, 2008

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Attachments: **Declaration of Dr. Paul Yaworsky under 37 CFR § 1.132**